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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/701,883

11/05/2003

Nabil L. Muhanna

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Holland & Hart, LLP (LANX, Inc.)
Intellectual Property Department
P.O. Box 8749
Denver, CO 80201-8749

EXAMINER

PRONE, CHRISTOPHER D

ART UNIT

PAPER NUMBER

3738

MAIL DATE

DELIVERY MODE

04/06/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|---|---------------------------------------|--|
| Office Action Summary | Application No. 10/701,883 | Applicant(s) MUHANNA ET AL. | |
| | Examiner CHRISTOPHER D. PRONE | Art Unit 3738 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4,6-13,15,16,18,20-23,25-30,41-45 and 48-50 is/are pending in the application.
- 4a) Of the above claim(s) 3,11-13,16,22,23,25,27-30 and 41-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4,6-10,15,18,20,21,26 and 48-50 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 2/10/09 has been entered.

The earliest support for the elected embodiment of this application is in provisional application 60476075. Therefore the priority date of this application is 6/5/03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1, 2, 4, 6-10, 15, 18, 20, and 48-50 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson United States Patent 6,890,355 in view of Brantigan United States Patent 5,192,327.

Michelson discloses a metal vertebral body replacement comprising a body 300, nonparallel top and bottom surfaces (shown best in figure 17) having a plurality of

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through holes and continuous grooves 314 and protrusions (5:62-65), two growth hole faces 310 (planar) and 312 (curved) having 4 through holes 319 and a curved anterior face 304. Michelson further discloses use of a second identical implant for insertion along side the first 300".

In regards to claim 2 the grooves on the top surface extend completely through a portion of the top surface.

In regards to claims 48-50 Michelson discloses a plurality of grooves that extend perpendicular to the posterior surface. The first groove on the top is clearly not aligned in the same plane as with the last groove on the bottom.

However Michelson fails to disclose a groove on the top surface that extends through the anterior and posterior faces.

Brantigan discloses a spinal implant comprising a body having a top surface with projections and grooves that extend generally along the top through the anterior and posterior faces in the same field of endeavor for the purpose of securing the implant to the implant site.

In view of Michelson's lack of specific disclosure for its textured upper surface it would have been obvious to one having ordinary skill in the art at the time the invention was made to provide continuous grooves and protrusions on the top surface as taught by Brantigan with the device of Michelson in order to provide an implant with continuous grooves and protrusions that extend through the anterior and posterior surfaces which will secure the implant to the implant site.

Claim 21 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson in view of Brantigan as applied to claims 1, 2, 4, 6-10, 15, 18, 20, and 48-50 above and further in view of United States Patent Paul et al 6,143,033.

The combination of Michelson and Brantigan discloses the invention substantially as claimed being described supra. However, combination fails to disclose making his device from the bone comprising the medullary cavity.

Paul teaches the use of an implant made from bone comprising medullary cavity in the same field of endeavor for the purpose of using natural materials that the body will accept and grow into.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine the bone material taught by Paul with the device of Michelson as modified by Brantigan in order to provide an implant made from all natural materials.

Claim 26 is rejected under 35 U.S.C. 103 as being unpatentable over Michelson in view of Brantigan as applied to claims 1, 2, 4, 6-10, 15, 18, 20, and 48-50 above and further in view of Wagner et al. United States Patent 5,306,309.

The combination of Michelson and Brantigan discloses the invention substantially as claimed being described above. However, the combination fails to disclose making his device from a plurality of bonded layers.

Wagner teaches the use of an implant comprising a base metal having layers bonded to its outer surface in the same field of endeavor for the purpose enhancing the implants material properties. (6:13-40)

It would have been obvious to one having ordinary skill in the art at the time the invention was made to make the implant of Michelson as modified by Brantigan out of a plurality of layers as taught by Wagner in order to provide an implant with enhanced durability or porosity.

Response to Arguments

Applicant's arguments with respect to all claims have been considered but are moot in view of the new ground(s) of rejection. However for clarity sake the examiner wishes to address the applicant's arguments directed at claim 48. In regards to claim 48, applicant argues that the Michelson discloses matching grooves on the implants top and bottom surfaces. However the applicant has not defined the claims so that every groove on the top surface must be considered a groove. Therefore the examiner is able to call one or more of the elements reference as element 314 on the top surface a through hole and the corresponding element on the bottom surface a groove. Therefore this interpretation allows for grooves to be aligned with holes not more grooves. Furthermore the applicants disclosure discloses both embodiments with the grooves aligned and embodiments with then not aligned. However the disclosure fails to provide a reason why one would choose one design over the other. Therefore this is clearly a matter of design choice that one of ordinary skill within the art would obviously make.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTOPHER D. PRONE whose telephone number is (571)272-6085. The examiner can normally be reached on Monday through Fri 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Christopher D Prone
Examiner
Art Unit 3738

/Christopher D Prone/

/Corrine M McDermott/

Supervisory Patent Examiner, Art Unit 3738